

**LifeSource Fertility Center**

**Joseph G. Gianfortoni, M.D.**

BOARD CERTIFIED OB/GYN  
REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY

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May 15, 2000

*In Vitro  
Fertilization*

*GIFT/ZIFT*

*Tubal Reversal*

*Operative  
Laparoscopy*

*Microsurgery*

*Laser Surgery*

*Ovulation  
Induction*

*Inseminations*

*Hirsutism*

*Menstrual  
Irregularities*

*Pelvic Pain*

*Endometriosis*

Dockets Management Branch (HFA-305)  
Food & Drug Administration  
5630 Fishers Lane, Rm 1061  
Rockville, MD 20852

To Whom It May Concern:

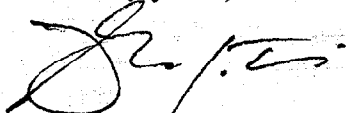
I am writing this letter in opposition to the proposed rules for "Suitability Determination for Donors of Human Cellular and Tissue-Based Products" in the September 30, 1999 Federal Register.

All egg donors are routinely tested for HIV and Hepatitis prior to the start of the donor IVF cycle. By requiring the freezing of the resultant embryos and six month quarantine after which the donor would be retested, the quality of embryos will be significantly diminished than when transferred immediately after the aspiration without freezing. This would result in a lower pregnancy rate. The couples that utilize these services typically have their biologic clocks ticking loudly. There are no known cases of infections originating from donor pre-embryo transfer when routinely tested prior to the aspiration.

If a couple were to fail in their initial attempt, then additional time and money would be necessary for successive and successful cycles. With donor pre-embryo transfer averaging 50%, why would the government want to decrease the success rate causing a large increase in typically out of pocket cost to these couples.

Please reconsider your decision and make appropriate allowances for this unique situation.

Cordially yours,



Joseph G. Gianfortoni, M.D.

JGG/jtd

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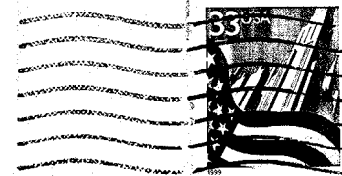
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